

IN THE CLAIMS:

Please cancel claims 6, 15 and 19.

Please amend claims 1, 7, 8, 9, 10, 11, 13, 14, 20 and 21 and add new claim 22 as follows:

Claim 1 (Amended). A method for assessing therapeutic effectiveness of a treatment agent for renal disease and/or renal complications of a disease, comprising:

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- (a) administering a treatment agent to a patient;
 - (b) obtaining a urine sample [of body fluid] from the patient;
 - (c) assaying for a protein in the urine sample by detecting the native protein

and intact modified form of the protein in the urine sample,

wherein presence of or lack of the protein in the urine sample or decreasing amount of the protein over time in the urine correlates with effectiveness of the treatment agent.

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Claim 7 (Amended). The method of claim 1, wherein the protein is selected from the group consisting of albumin, globulin, alpha-globulin, alpha₁-globulin, alpha₂-globulin, beta-globulin, gamma-globulin, euglobulin, pseudoglobulin I and II, fibrinogen, alpha₁ acid glycoprotein (orosomucoid), alpha₁ glycoprotein, alpha₁ lipoprotein, ceruloplasmin, alpha₂ 19S glycoprotein, beta₁ transferrin, beta₁ lipoprotein, immunoglobulins A, E, G and M, horseradish peroxidase, lactate dehydrogenase, glucose oxidase, myoglobin, lysozyme, protein hormone, growth hormone, insulin and parathyroid hormone.

Claim 8 (Amended). The method according to claim 1, wherein the assaying for a protein in the urine sample comprises [a method selected from the group consisting of:

- (a) assaying for albumin by a conventional method; and
- (b)] assaying for native and intact modified albumin.

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Claim 9 (Amended). The method according to claim 8, wherein the assaying comprises:

- (a) an antibody method, and
- (b) a non-antibody method comprising chromatography, electrophoresis or sedimentation of the sample to test for the presence of native or intact modified albumin.

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Claim 10 (Amended). The method of claim 9, wherein the albumin is detected by an antibody or antibodies specific for both unmodified and modified forms of albumin.

Claim 11 (Amended). The method according to claim 9, wherein the albumin is detected by an antibody that is specific for the modified albumin.

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Claim 13 (Amended). The method according to claim 1, wherein the assaying for a protein in the sample comprises the steps of; and

- (i) detecting the native protein amount by conventional antibody assay;
- (ii) detecting the native plus intact modified protein by a non-antibody method.

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Claim 14 (Amended). The method according to claim 13, wherein the non-antibody method comprises chromatography, electrophoresis or sedimentation of the sample to test for native or intact modified.

Claim 20 (Amended). A method for identifying a treatment agent for renal disease and/or renal complications of a disease, comprising:

- (a) administering a candidate therapeutic agent to a patient;
- (b) obtaining a series of urine samples from the patient over time; and
- (c) assaying for a protein in each of the samples in the series of samples by a

non-antibody assay or an antibody assay which measures both native form of the protein and intact modified form of the protein,

wherein a decreasing amount of the protein over time in the urine indicates that the candidate therapeutic agent is a treatment agent for the renal disease and/or the renal complications of a disease.

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Claim 21 (Amended). The method of claim 19, wherein assaying for a protein in the samples comprises assaying for a modified form of albumin, wherein decreasing amount of the modified form of the albumin over time in the urine indicates that the candidate therapeutic agent is a treatment agent for the renal disease and/or the renal complications of a disease.

Please add the following new claims:

Claim 22 (New). The method according to claim 13 wherein the protein is albumin.

97 Claim 23 (New). The method of claim 20 wherein an antibody assay is used in step (c).